510(k) Summary
510(k) Number K09 / 752 P. 1 of 2

Viztek, Inc.
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Jacksonville, FL 32217
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Date Prepared: May 27, 2009 NOV 12 2009
Contact: Bruce Ashby, Sales and Marketing Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: Viztek WL Series Digital Diagnostic Digital X-Ray Systems (Multiple Models)
   Classification Name: Stationary x-ray system, Product Code 90 KPR and Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB,
   Common/Usual Name: Digital Stationary Diagnostic X-Ray System

2. **Equivalent legally marketed device**: K082604, VIZTEK DR, MODELS: DR1000, DR3000, DR4000 and K090625, WIRELESS PORTABLE DETECTOR FD-W17, PHILIPS MEDICAL SYSTEMS NORTH AMERICA CO (This is the 510(k) for the wireless panel); K003438.SmartRad, CMT Medical Technologies. (This is the 510(k) for the software)

3. **Indications for Use (intended use)** This digital radiographic system is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Excludes fluoroscopy, angiography, and mammography.

4. **Description of the Device**: This digital diagnostic x-ray system consists of a tubehead/collimator assembly mounted on a ceiling suspension OR a U-Arm, along with a generator, generator control, and an elevating x-ray table. Power ratings for the available generators are in the rage of 50 kw to 80 kW. Exposure voltage range varies from 40 – 125 KV or 40 – 150 kV with current of 300 - 100 mA. Exposure time is 1 ms – 10 s. Models: Model DR3000 (U-arm single detector) and Model DR4000 (dual detector-ceiling suspension and table and upright bucky) and DR1000 single detector (standing bucky and ceiling suspension. The digital panel is the Pixium 3543pR (K090625) and the digital subsystem is the SmartRad, CMT Medical Technologies, K003438.

5. **Safety and Effectiveness, comparison to predicate device**. The results of bench and test laboratory indicates that the new device is as safe and effective as the predicate devices.

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6. Substantial Equivalence Chart

Characteristic	K082604, VIZTEK DR, MODELS: DR1000, DR3000, DR4000 and	Viztek WL Series
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	SAME, but updated: "Excludes fluoroscopy, angiography, and mammography." (Statement added for the sake of clarity)
Configuration	U-Arm mount or Ceiling Suspension	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal	SAME
Digital Panel	Pixium 4600 Pixel size 143 µm 3000 x 3000 pixels	Pixium 3543pR (K090625) Pixel size 144 µm 2372 x 3000 pixels
Software	Employs K003438.SmartRad, CMT Medical Technologies.	SAME
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. Conclusion

After analyzing bench and external laboratory testing to applicable standards, it is the conclusion of Viztek Inc that the Viztek WL Digital Diagnostic X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

NOV 12 2009

Viztek, Inc.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer, Submission Correspondent
Kamm & Associates
333 Milford Rd.
DEERFIELD IL 60015

Re: K091752
Trade/Device Name: Viztek WL Diagnostic Digital X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: September 9, 2009
Received: September 11, 2009

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091752

Device Name: Viztek WL Diagnostic Digital X-Ray System

Indications For Use:
This Digital Radiographic System is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Excludes fluoroscopy, angiography, and mammography.

Prescription Use X AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091752